

5 The Examiner has rejected claims 9, 10, 14, 16, 18, 21, 22 and 27 under 35 U.S.C. §112, second paragraph, citing various instances of alleged indefiniteness. Each specific point raised by the Examiner will be addressed in turn.

10 In response to the Examiner's objection to claim 10, applicant has amended the claim to clarify that the lactic acid salt required in claim 1 is required in claim 10 to be a mixture of both inorganic and organic lactic acid salts.

In response to the Examiner's observations regarding claims 9 and 22, applicant has amended the claims to indicate that the polymer must contain 2 or more monomeric units.

15 The Examiner has objected to the term "organic lactic acid salt" in claims 14, 16, 21 and 27, arguing that it is redundant in so far as lactic acid is organic. Applicant respectfully traverses the Examiner's objection to this term.

20 In the present specification, for example at page 11, line 19 through page 14, line 30, applicant has carefully laid out its definition for the terms "inorganic lactic acid salt" and "organic lactic acid salt." Applicant urges that the specification clearly
25 discloses that the term "organic lactic acid salt" includes salts in which the cation is an organic species; the organic nature of lactate is irrelevant to this definition. Therefore, applicant urges that the rejected claims possess the definiteness required by 35
30 U.S.C. §112, second paragraph.

Finally, applicant has amended claim 18 in order to incorporate the Examiner's kind suggestions regarding the nature of the components which make up the required salt.

Therefore, applicant urges that all claims presented fully comply with the dictates of §112, second paragraph.

5 Turning now to the rejections based on the prior art, the Examiner has rejected claims 1-4, 10-12, 14, 15, 17, 23 and 24 under 35 U.S.C. §102(b) as being anticipated by Kober. Applicant respectfully traverses the Examiner's rejection.

10 The Examiner characterizes the Kober reference as teaching the use of organic and/or inorganic lactates, including sodium lactate, as nutritional supplements, and the inclusion of fruit juices as meeting the requirement for carbohydrates in certain dependent claims. Applicant urges that the Examiner has
15 characterized the Kober reference in an overly-broad fashion and failed to appreciate that the functional language included in the claims provides a clear distinction which avoids any anticipatory effect.

20 In addition, applicant has amended claims 1 and 14 in order to highlight the important differences between the claimed invention and the references of record.

The Kober reference utilizes sodium and other alkaline metal lactate salt solutions as a menstruum to prevent the precipitation of salts in strong mineral
25 supplementation solutions. Although the distinct purpose would not seem to effect Kober's value as an anticipatory reference, such is the case. The mineral salt concentrations present in the disclosure of Kober are far too concentrated, and the presence of lactate
30 is far too minimal, to have the effect required by the functional language of the claims.

In this regard, the Examiner's comment that the requirement to "supply nutritional supplementation to mammals" is clearly met by Kober highlights this
35 misconception. In Kober, it is the mineral salts which

are intended to supply nutritional supplementation; the lactate serves merely as a means for keeping those salts in solution. It is not Kober's intent to utilize lactate as a source of nutritional supplementation such as is the express purpose of the present invention.

Similarly, the Examiner's indication that fruit juice (known to contain fructose) is an acceptable means to deliver Kober's mineral food supplement fails to appreciate the special nature of using fructose together with lactate as a nutritional supplement. It is only in the present invention that one is taught to utilize fructose for its beneficial effects, i.e. being metabolized in the body by the same pathway as lactate, therefore enhancing the benefits of lactate nutrition.

Furthermore, Kober makes no mention of using organic salts of lactic acids; his off-hand reference at column 2, line 97, to organic lactate constituting only an obscure reference which raises the confusion which concerned the Examiner previously.

Finally, it is only in the teaching of the present application that the benefits of using a lactate-based nutritional supplement as a means of enhancing absorption of other key nutrients during exercise and recovery is described. Kober, as might be expected, is silent on this issue.

Therefore, applicant urges that, giving due regard to the import of all limitations in the claims, Kober can not be said to anticipate the present invention.

The Examiner has further rejected claims 1-7, 10-20, and 23-27 under 35 U.S.C. §103 as being obvious over Millman in view of Kober. Applicant respectfully traverses this rejection as well.

Applicant notes that Millman proposes an optimal mixture of amino acids and complex carbohydrates for athletes but that there is no claim or disclosure for the use of lactates as a major energy source or means for enhancing absorption of other nutrients during and after exercise. However, the Examiner's assertion that a skilled artisan would combine the disclosure of Millman with the disclosure of Kober constitutes an improper attempt to reconcile the vastly disparate nature of these two references. Nowhere in either reference is there a recognition that lactate can comprise an important source of nutrition and other benefits in a nutritional supplement. Even if, as asserted by the Examiner, a skilled artisan would utilize at least one lactate salt by a reasonable expectation of improving the stability of Millman's composition, there is no express motivation to include a sufficient amount of such salt so as to have any beneficial effects on the actual nutrition of the host mammal.

The Examiner has further rejected claims 1-27 under 35 U.S.C. §103 as being obvious over Adibi et al. in view of Kawajiri. Applicant respectfully traverses this rejection as well.

As urged with respect to the combination of references discussed above, due to their entirely different intent and purposes the combination of Adibi and Kawajiri do not render the subject invention obvious because they would not teach one of ordinary skill in the art to utilize lactate salts as a major component of a nutritional supplement.

The nutrient composition of Adibi, containing 40 to 50% polypeptide and amino acid, is far too concentrated to be of any use to an athlete during severe exercise. Such concentrated solutions would cause transient dehydration in athletes and result in

nitrogen toxicity during exercise. In the present invention, amino acids are used as ionic carriers of lactate anion and, as such, the concentration will be far less than that disclosed by Adibi et al.

5 Similarly, Kawajiri utilizes lactic acid (not lactate) and other acids, such as hydrochloric, sulfuric and phosphoric acid, to prevent the browning discoloration caused by the Maillard reaction in parenteral nutrition solutions containing dextrose and
10 amino acids. Thus, the lactic acid in Kawajiri is used as a stabilizing agent, similar to the use prescribed in Kober, and there is no teaching that lactate can be used to deliver carbohydrate energy and other nutrients to athletes engaged in strenuous exercise.

15 Therefore, the combination of Adibi and Kawajiri is not seen to render the present nutritional supplement obvious.

In sum, although the Examiner argues that all aspects of the invention are found in the various cited
20 references, applicant has shown that certain of these references cannot be used to support the Examiner's basic assertions.

Furthermore, even assuming that the references could be combined to teach all of the elements of the
25 present invention, there is no suggestion in any of the references or any combination thereof that such combination could be made. Applicant points out that "[o]bviousness cannot be established by combining the teachings of the prior art to produce the claimed
30 invention, absent some teaching suggestion or incentive supporting the combination." In re Geiger, 2 U.S.P.Q.2d 1276, 1278 (Fed.Cir. 1987).

The PTO has the burden of establishing a prima facie case of obviousness under 35 U.S.C. §103. It
35 must show that some objective teaching in the prior art

or knowledge generally held by one of ordinary skill would lead an individual to combine the relevant teachings of the references. In re Fine, 837 F.2d 1071, 1074 (Fed.Cir. 1988). Therefore, a combination of relevant teachings alone is insufficient grounds to establish obviousness, absent some teaching or suggestion to do so. Id. at 1075:

[I]t is impermissible to use the claims as a frame and the prior art references as a mosaic to piece together a facsimile of the claimed invention. W.L. Gore & Assoc. v. Garlock, Inc., 721 F.2d 1540 (Fed.Cir. 1983).

The applicant recognizes that certain features of the invention are disclosed in various ones of the references cited by the Examiner. Nevertheless, none of the references teaches the unique combination of features capable of performing the functions called for in the claims. It is impermissible hindsight reasoning for the Examiner to pick a feature here and there from among the references to construct a hypothetical combination which obviates the claims. As stated in the case of In re Fine, 837 F.2d at 1075, quoting from ACS Hospital Systems, Inc. v. Montefiore Hospital, 221 U.S.P.Q. 929 (Fed.Cir. 1984):

[obviousness] cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination . . . And teachings or references can be combined only if there is some suggestion or incentive to do so.

A large number of references may exist in the prior art where, if the prior art be disregarded as to its content, purpose, mode of operation and general context, the several elements contributing to the invention claimed by the applicant, if taken individually, may be disclosed. However, the important thing to recognize is that the reason for combining these references in any way to meet applicant's claims

only becomes obvious, if at all, when considered from hindsight in the light of the application disclosure. The Federal Circuit has stressed that the "decisionmaker must step backward in time and into the shoes worn by a person having ordinary skill in the art when the invention was unknown and just before it was made." Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1566 (Fed.Cir. 1987). To do otherwise would be to apply hindsight reconstruction, which is strongly discouraged by the Federal Circuit. Id. at 1568; In re Fine, 837 F.2d at 1075; In re Dow Chemical, 837 F.2d 469 (Fed.Cir. 1988). In W.L. Gore & Assoc. v. Garlock, Inc., 721 F.2d 1540 (Fed.Cir. 1983), the Court states:

To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher. Id. at 1553.

Therefore, without some reason or suggestion in the references to combine relevant prior art teachings, the Examiner has failed to establish a prima facie case for obviousness.

The argument is sometimes made, citing In re Sernaker, 702 F.2d 989, 217 U.S.P.Q. 1 (Fed.Cir. 1983) and In re Nilssen, 851 F.2d 1401, 7 U.S.P.Q.2d 1500 (Fed.Cir. 1988), that no express suggestions in the references for the combination of references is necessary. However, this begs the question. The issue is whether the references as a whole suggest the combination being used to obviate the claims. As stated in Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143 (Fed.Cir. 1985):

When prior art references require selective combination by the court to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself. ACS hospital Systems, Inc. v. Montefiore Hospital, 732 F.2d 1572, 1577 & n. 14, 221 USPQ 929, 933 & n. 14 (Fed.Cir. 1984). There must be 'something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination.' Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick Co., 730 F.2d 1452, 1462, 221 USPQ 481, 488 (Fed.Cir. 1984).

Not only must the claimed invention as a whole be evaluated, but so also must the references as a whole, so that their teachings are applied in the context of their significance to a technician at the time -- a technician without our knowledge of the solution.

Simply stating that the invention would have been obvious to a person of ordinary skill is also insufficient, for the assertion must be supported by clear and convincing evidence. Pandiut Corp. v. Dennison Mfg. Co., 810 F.2d at 1568.

Furthermore, it is important to stress that obviousness is not established if a person of ordinary skill might find it obvious to try various combinations of the relevant teachings. "This is not the standard of 35 U.S.C. §103." In re Geiger, 815 F.2d at 688.

Thus, applicant again urges that the present rejections are not supported by the cited combination of prior art.

Applicant believes that the instant amendments and remarks obviate all grounds for rejection of the claims. Reconsideration of the application and its early allowance are respectfully requested.

The Examiner is authorized to contact applicant's undersigned representative by telephone, collect, at (415) 433-4150 if, in the opinion of the Examiner, an interview will in any way expedite the prosecution of this application.

Respectfully submitted,

LIMBACH & LIMBACH

Date: 13 January 1992

By: *James C. Weseman*
James C. Weseman
Reg. No. 30,507
Attorneys for Applicant

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